



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Date: SEP 30 2013

Request Number: 2013-7321

Jason Smathers
Muckrock News
P.O. Box 55819
Boston, MA 02205-5819

Subject of Request: Divestiture memos

Dear Sir/Madam:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA). I apologize for any delay in responding to you. The paragraphs checked below apply to your request:

☐ We have already released certain materials to you and are denying the remainder of your request.

☒ We are denying your entire request.

☒ The following exemption(s) of FOIA, 5 U.S.C. 552, indicated by an "X" is/are the authority for denying you access to the non-disclosable material. We have enclosed copies of FOIA and regulations for your information.

- ☐ (b)(1) National security information concerning the national defense or foreign policy
- ☐ (b)(2) Internal rules and practices
- ☒ (b)(3) Prohibited from disclosure by other laws
- ☐ (b)(4) Trade secret and confidential commercial information
- ☐ (b)(5) Certain interagency and intra-agency communications
- ☒ (b)(6) Information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy
- ☐ (b)(7) Records or information compiled for law enforcement purposes when disclosure
 - ☐ (A) could reasonably be expected to interfere with enforcement proceedings
 - ☐ (B) would deprive a person of a right to a fair trial or an impartial adjudication
 - ☐ (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy

- ☐ (D) could reasonably be expected to disclose the identity of a confidential source
- ☐ (E) would disclose techniques, procedures or guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law
- ☐ (F) could reasonably be expected to endanger the life or physical safety of an individual

[X] The following section(s) of the implementing regulations of the Department of Health and Human Services (DHHS) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

- | | |
|-------------------------------|----------------------------------|
| <input type="checkbox"/> 5.63 | <input type="checkbox"/> 5.68(a) |
| [X] 5.64 | <input type="checkbox"/> 5.68(b) |
| <input type="checkbox"/> 5.65 | <input type="checkbox"/> 5.68(c) |
| <input type="checkbox"/> 5.66 | <input type="checkbox"/> 5.68(d) |
| [X] 5.67(a) | <input type="checkbox"/> 5.68(e) |
| | <input type="checkbox"/> 5.68(f) |
| | <input type="checkbox"/> Other: |

[X] The following section(s) of the implementing regulations of FDA and reason(s) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 21.

[X] 20.63 Personnel, medical, and similar files, the disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

[X] FDA's Regulations at CFR Part 20 are available at:
http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html

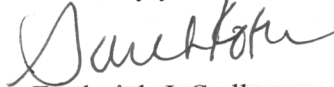
[X] Other laws, in addition to FOIA, may prohibit disclosure of the information you requested. The following law(s) applicable to this denial is/are indicated by an "X".

- ☐ 18 U.S.C. 1905 [Federal Trade Secrets Act]
- ☐ 21 U.S.C. 331(j) [Federal Food, Drug, and Cosmetic Act]
- ☐ 21 U.S.C. 360j(c) [Federal Food, Drug, and Cosmetic Act]
- [X] 5 U.S.C. 107(a)(2) Appendix 4 [Ethics in Government Act]

[X] The estimated volume of the records we are denying is: 20 divestiture memos.

The Department of Health and Human Services= implementing regulations, 45 CFR 5.34, set forth the procedures for you to follow if you decide to appeal this decision not to provide you with the information you requested. Your appeal should be sent within 30 days from the date you receive this letter to the Director, News Division, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services. Should you choose to send your appeal through the U.S. Postal Service, please mail it to 7700 Wisconsin Avenue, Suite 920, Bethesda, MD 20857. Should you choose to send your appeal through a private courier service, please send it to 7700 Wisconsin Avenue, Suite 920, Bethesda, MD 20814. Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

Sincerely yours,



Frederick J. Sadler

Director

Division of Freedom of Information

